

Kawasaki relates to a compressive hemostatic belt designed to apply pressure to an area of the body to stop bleeding. Accordingly, it is not an ostomy device. It is not intended to, and is not capable of, controlling the passage of liquid and solid waste material through a stoma. It is designed for use with an insertion wound to stop the bleeding associated with the wound to promote healing of the wound.

Kawasaki discloses the use of adhesive plasters 14 and 15. However, those adhesive plasters are not adapted to surround the wound and do not secure any part of the hemostatic belt to the body surrounding the wound using adhesive. In that regard, Kawasaki teaches, at column 9, lines 25-28 "... the strip 1 is wrapped around the patient's waist and the end is locked as by a fabric adhesive plaster 14, while a fabric adhesive plaster 15 is applied to a portion of the body and the strip 1 to prevent deviation."

Figures 22a and 22b illustrate the function of the Kawasaki adhesive plasters 14 and 15. It is clear from those figures that adhesive plasters 14 and 15 do not surround the wound and do not secure any part of the hemostatic belt to the body surrounding the wound. The adhesive plasters are used to keep the belt in place on the body. It is well known that the removal of a bandage which is adhesively attached to the skin adjacent a wound will result in damage to the wound, unless a special type of easy release adhesive is used. It is for that reason that Kawasaki, which does not teach the use of a special easy release adhesive on the plasters, employs gauze which is interposed between the belt and the insertion wound to avoid contact between the belt and the wound, and that the adhesive plasters are situated so as not to directly engage the skin adjacent the insertion wound.

Specifically, Kawasaki teaches the use of gauze 10 situated between the balloon pocket and the wound such that only the gauze contacts the wound. A fabric adhesive plaster 14 is provided to lock the end of strip 1 to the exterior surface portion of strip 1 so the belt remains securely around the patient. However, plaster 14 does not touch or adhere to the skin. A fabric adhesive plaster 15 is situated between the body of the patient and strip 1 “to prevent deviation” (movement of the belt relative to the body) but at a location on the body remote from the wound, such that the adhesive in the plaster does not contact the skin adjacent to the wound.

The reason why Kawasaki uses gauze between the belt and the insertion wound and avoids having any adhesive bearing portion of the belt engage the skin adjacent the wound is because the type of adhesive used by Kawasaki would damage the wound upon removal if it were in direct contact with the skin adjacent the wound.

The secondary references, Wagner, Lloyd and Barakat, all relate to ostomy devices. Ostomy devices by their nature require a complete seal between the device and the skin surrounding the stoma to perform their intended function of controlling the passage of liquid and solid waste material through the stoma. Thus, each of the secondary devices teaches sealing the faceplate of the ostomy device to the skin surrounding the stoma using a special adhesive that releases easily such that removal of the device does not damage the wound.

Because Kawasaki is a compressive hemostatic belt which avoids direct contact with the wound by interposing gauze therebetween, and does not use adhesive to secure the belt to the skin surrounding an insertion wound, and all of the secondary references relate to ostomy devices that require direct contact between the device and the stoma and

use adhesive to seal the faceplate to the skin surrounding the stoma, the proposed combination of the primary reference with the secondary references is inappropriate.

One skilled in the art of designing compressive hemostatic belts to stop bleeding from insertion wounds would not be taught by the secondary ostomy device references to modify Kawasaki to eliminate the gauze interposed between the belt and the wound and to alter the position and purpose of the adhesive plasters, as well as the type of adhesive used on the plasters. That is because would be no advantage in making those modifications. The Kawasaki belt is presumably capable of fulfilling its purpose without such modification.

The Barakat reference addresses this very issue. It teaches that the use of a special type of easy release adhesive is critical in an ostomy device to avoid damaging the wound when the ostomy device is removed:

[0008] As patients and caretakers are aware contact of such a high strength, e.g. hydrocolloid, adhesives with the sensitive stoma tissue is of course to be avoided, since the stoma tissue may otherwise suffer damage. Contact of a conventional high strength adhesive with stoma tissue potentially even leads damage and even to removal of the portions of the stoma tissue. The detrimental effect of the ostomy device on the stoma tissue over prolonged periods of attachment and removal of such devices, has even led to situations, where a patient had to undergo further medical operations in which a new artificial passage by the use of new stoma tissue was provided.

[0032] While it is important to keep the abdominal skin in a healthy condition, it is even more critical to protect the stoma from damage. Such damage includes for example removal of portions of the tissue as may happen when removing an ostomy device due to mechanical impact or due to contact with a strong adhesive. As the stoma tissue does not comprise nerves such damage is painless, however, nonetheless critical as the stoma tissue will not reproduce itself and damage may alternatively lead to the need to undergo a further ostomy operation.

[0039] It is critical for the method of the present invention that the right type of adhesive is used. Suitable adhesives are all adhesives compatible with abdominal skin and/or stoma tissues. Hence adhesives which do not damage the skin or the stoma and which are easily and painlessly removable and which do not leave too much residue. Particularly suitable adhesives and their properties are described hereinafter.

[0040] When a conventional ostomy device is provided with an adhesive disclosed herein the device can be attached so that it predominately sticks to the abdominal skin, however, portions of the adhesive also being in contact with the stoma. This allows to provide ostomy devices which more closely conform to the stoma and hence minimize the exposure of the abdominal skin to bodily fluids such as faecal material. When such an ostomy device is removed the stoma will not be damaged.

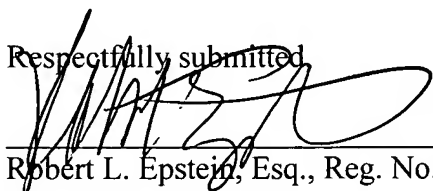
Accordingly, the combination of Kawasaki and the secondary ostomy device references is inappropriate. Even if it were not inappropriate, the proposed combination would not lead one skilled in the art to the claimed invention.

Kawasaki is not an ostomy device. It is designed for a different purpose (apply pressure on an insertion wound to stop bleeding) than ostomy devices (which are designed to control the passage of waste through the stoma). Kawasaki teaches away from securing the belt directly to the body by interposing gauze between the belt and the wound and by not using adhesive to secure the belt to the skin surrounding the wound. That is for the very same reason that the ostomy devices of the references teach the use of special easy release adhesive so as not to damage the wound as the belt is removed.

Claims 41, 56 and 45 are each rejected under 35 USC 103(a) as unpatentable over Kawasaki alone or Kawasaki in view of Wagner, Lloyd and Barakat, and further in view of an additional reference. However, since Kawasaki alone or in view of the other references does not teach the limitations of the independent claims 35 and 59, these rejections cannot be sustained and should be withdrawn.

A Request for Continued Examination and the required fee is presented to permit consideration of the arguments presented herein.

Respectfully submitted



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